

August 22, 2006
Mr. Oscar Hernandez, Director
Risk Assessment Division
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

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supresta
BUILT-IN DEFENSE

201-16343

Re: Fyrol 6

Dear Mr. Hernandez:

Supresta is very pleased to submit the enclosed revised Robust Summary Dossier for Fyrol 6 (CAS No. 2781-11-5) in fulfillment of its commitment to the EPA High Production Volume Challenge Program for this material. The original robust summaries for Fyrol 6, first submitted to you in December, 2003, have been extensively revised, with additional robust summaries added.

The Fyrol 6 HPV Test Plan required the conduct of five GLP compliant tests, to determine melting point, hydrolysis, acute toxicity to aquatic invertebrates, acute toxicity to aquatic plants, and reproductive/developmental toxicity. Supresta is pleased to report that all five tests have been completed, with a boiling point test substituted for melting point since the product is a liquid.

Supresta has reviewed the Agency's comments received in June, 2004, on the initial submission of Fyrol 6 robust summaries, and was pleased to learn that the Agency agreed with the proposed test plan with one exception. EPA suggested that an OECD 422 guideline be followed rather than OECD 421, because of "excess mortality" reported in the repeated-dose toxicity study. Supresta has carefully examined the data from the repeated-dose toxicity study and believes it to be a valid subchronic study, for the following reason. Although an increase in mortality was observed due to gavage dosing of Fyrol 6 rather than dietary administration, this was more than offset by using 22 animals per sex per dose group rather than the guideline requirement of 10 animals per sex per group. Thus a sufficient number of animals were available for examination at the end of the repeated-dose study, allowing for the conduct of an OECD 421 study.

Robust summaries for the new boiling point, hydrolysis, aquatic invertebrate toxicity, algal toxicity, and reproductive/developmental tests are included in the enclosed revised dossier. Supresta is very pleased to submit, herein, the final set of robust summaries to complete its commitment to the High Production Volume Challenge Program.

We appreciate the opportunity to participate in the program.

Sincerely yours,

Andy Wang, Ph.D.
Manager, Regulatory Affairs

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